

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 32

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte WOO-BAEG-CHOI, GUY R. HUMPHREY, PAUL J. REIDER,
ICHIRO SHINKAI, ANDREW S. THOMPSON
and RALPH P. VOLANTE

Appeal No. 1996-4090
Application No. 08/241,958

ON BRIEF

Before JOHN D. SMITH, OWENS, and LIEBERMAN, **Administrative Patent Judges.**
LIEBERMAN, **Administrative Patent Judge.**

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the examiner's refusal to allow claims 1 through 5, 9, 11, 12, 16 and 17 which are all the claims remaining in the application.

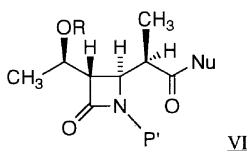
THE INVENTION

The invention is directed to various processes for the preparation of carbapenem intermediates. In one aspect of the invention a decarboxylation reaction occurs. In a second aspect, a nucleophilic reaction on a substituted Meldrum's acid moiety results in a ring opening to form a carboxylic acid moiety and substitution of a nucleophile on the remaining carbonyl moiety. The invention is further illustrated by the claims appended below.

THE CLAIMS

Claims 1 and 5 are illustrative of appellants' invention and are reproduced below.

1. A process for making a beta methyl carbapenem intermediate of formula VI:



wherein

- R is
- (a) hydrogen,
 - (b) methyl, or
 - (c) a hydroxy protecting group;

Claim 2 stands rejected under 35 U.S.C. § 103 as being unpatentable over Vig I, Vig II or Heisig in view of Favara, Hurd or Arcadi.

OPINION

We have carefully considered all of the arguments advanced by appellants and the examiner and agree with appellants that the aforementioned rejections under 35 U.S.C.

§ 103 and 35 U.S.C. § 112 are not well founded. Accordingly, we do not sustain the examiner's rejections.

The Rejection under Section 112

Any analysis of the claims for compliance with 35 U.S.C. § 112 should start with the second paragraph, then proceed with the first paragraph. In re Angstadt, 537 F.2d 498, 501, 190 USPQ 214, 217 (CCPA 1976); In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238, (CCPA 1971).

The legal standard for definiteness under the second paragraph of 35 U.S.C.

§ 112 is whether a claim reasonably apprises those of ordinary skill in the art of its scope. See In re Warmerdam, 33 F.3d 1354, 1361, 31 USPQ2d 1754, 1759 (Fed. Cir. 1994). The inquiry is to determine whether the claim sets out and circumscribes a particular area with a reasonable degree of precision and particular definiteness of the language employed in a claim must be analyzed not in a vacuum, but in light of the teachings of the particular application. See In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971).

Accordingly, it is incumbent upon the examiner, in the first instance, to demonstrate that one of ordinary skill in the art would not understand the scope of the claim when the claim language is read in light of the specification and the state of the prior art. In the present case, the examiner has not satisfied this burden. It is the examiner's position that the terms, "to yield a 95.5 ratio," "mild acid," and, "nucleophile" are indefinite. See Answer, pages 3-5. However, the specification sets forth in example 5 an aliquot assay showing a mixture of 95.5 ratio of S to " methyl product. Nonetheless, the examiner argues that the phrase is indefinite because other runs or other mild acids could result in different ratios. However, even if the examiner were correct, the argument is not relevant. The metes and bounds of the claimed subject matter are clear when read in light of the specification.

As to the balance of the terms rejected by the examiner, acids utilized are taught at page 9, lines 7-10. Nucleophiles are taught at pages 10, 11 and beginning again at page 13. On this record, we conclude that the specification provides a reasonable standard for understanding the metes and bounds of each of the claims when the claim is read in light of the specification. Accordingly, we reverse the rejection of the examiner.

We turn next to the examiner's rejection under the first paragraph of 35 U.S.C.

§ 112 on the grounds of lack of enablement. When rejecting a claim under the enablement requirement of section 112, the PTO bears the initial burden of setting forth a reasonable explanation as to why it believes the scope of protection provided by the claimed subject matter is not adequately enabled by the description of provided in the specification of the application. This includes providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement. If this burden is met, the burden then shifts to the applicants to provide suitable proof that the specification is enabling. See In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369

(CCPA 1971). Contrary to the requirements of the statute, the examiner has provided ample rationale that the claimed subject matter is fully enabled. See Answer, pages 4 and 5. The examiner's position is not that the claimed subject matter is not enabled in the specification, but that the claimed process does not recite the steps that the examiner believes critical. However, the basic issue before us is whether the claimed subject matter is adequately enabled. In this respect, we find that the specification in Example 1 fully enables the subject matter claimed by appellants. Accordingly, as the examiner fails to address the basic issue as to whether the claimed subject matter is enabled, we will not sustain the rejection of the examiner.

The Rejection under Section 103—Obviousness

"[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a prima facie case of unpatentability." See In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). The examiner has submitted five different rejections of the claimed subject matter based upon the prior art references discussed by the examiner are directed to organic syntheses similar to the processes required by the claimed subject matter, albeit without teaching either the starting materials or the final products. It is the examiner's position that each of the prior art processes directed to organic syntheses could be modified such that their use would result in the particular beta methyl carapenem intermediates of the claimed subject matter. The analysis submitted by the examiner, at the time of the Answer, was reasonable, appropriate and in accordance with the law as it was then understood. However, the test for obviousness is not whether one compares the claimed subject matter as a whole with the prior art to which said subject matter pertains. Although the prior art references teach the use of various processes of the claimed subject matter including decarboxylation, and nucleophilic attacks on Meldrum's acid, the prior art is not directed to the class of beta methyl carapenems required by the claimed subject matter. The mere possibility that the processes could be modified such that their use would lead to the particular intermediates recited in the claimed subject matter do not make the claimed processes obvious absent a suggestion in the prior art of the desirability of such a modification. Moreover, none of the references contain any suggestion or motivation to modify an azetidinone to obtain the particular carapenem intermediates of the claimed subject matter. The absence of that suggestion or motivation in and of itself is sufficient to conclude that no prima facie case of obviousness had been established. Ochai, 71 F.3d 1565, 1569-1570, 37 USPQ2d 1127, 1131-1132 (Fed. Cir. 1995).

DECISION

The rejection of claims 1 through 5, 9, 11, 16 and 17 under 35 U.S.C. § 112, first and second paragraphs as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the invention which applicant regards as the invention is reversed.

The rejection of claims 1, 11 and 12 under 35 U.S.C. § 103 as being unpatentable over Vig I, Vig II or Heisig is reversed.

The rejection of claim 5 under 35 U.S.C. § 103 as being unpatentable over Favara, Hurd or Arcadi is reversed.

The rejection of claims 1, 2, and 5 under 35 U.S.C. § 103 as being unpatentable over Barton is reversed.

The rejection of claims 16 and 17 under 35 U.S.C. § 103 as being unpatentable over Barton or Arcadi is reversed.

The rejection of claim 2 under 35 U.S.C. § 103 as being unpatentable over Vig I, Vig II or Heisig in view of Favara, Hurd or Arcadi is reversed.

The decision of the examiner is reversed.

REVERSED

JOHN D. SMITH
Administrative Patent Judge

TERRY J. OWENS
Administrative Patent Judge

PAUL LIEBERMAN
Administrative Patent Judge

)
)
)
)
)
) BOARD OF PATENT
) APPEALS
) AND
) INTERFERENCES
)
)
)

Appeal No. 1996-4090
Application No. 08/241,958

MERCK & CO., INC.
PATENT DEPT.
P.O. BOX 2009 - RY60-30
RAHWAY, NJ 07065-0907

Leticia

Appeal No. 1996-4090
Application No. 08/241,958

APJ LIEBERMAN

APJ JOHN D. SMITH

APJ OWENS

DECISION: REVERSED
Send Reference(s): Yes No
or Translation (s)
Panel Change: Yes No
Index Sheet-2901 Rejection(s):

Prepared: July 13, 2001

Draft Final

3 MEM. CONF. Y N

OB/HD GAU

PALM / ACTS 2 / BOOK
DISK (FOIA) / REPORT